

multi-layer plastic container having at least three layers and including an intermediate layer of a cyclic olefin copolymer. Paragraphs 12 and 13 of the Office Action. However, Meierhoefer and Itoh fail to disclose the polyolefin-polycycloolefin blend in the claimed ratios of the intermediate layer of the container. Paragraph 18 of the Office Action.

In this regard, the Examiner cites the new reference to Ding which discloses a container for medical fluids of a polymer composition of a polyolefin and a polycycloolefin. Therefore, in the Examiner's opinion, it would have been obvious to "modify Meierhoefer and Itoh with the polyolefin-polycycloolefin blend as taught by Ding, since Meierhoefer calls for forming a container, filling it with fluid and sealing it." Paragraph 22 of the Office Action.

As noted previously, the present invention is focused on the use of a drug solution filling plastic ampoule and the fact that it has to be opened by wrenching a holder tab off from a fusion-bonded portion. Thus it is necessary to provide excellent operability of the plastic ampoule while maintaining sufficient barrier properties. The present inventors discovered that if the layered structure of the ampoule had an intermediate layer composed of blends of 20 to 50 wt% of a polyolefin and 50 to 80 wt% of a polycycloolefin that it had both excellent openability, while maintaining good barrier properties.

In this regard, Ding does not provide any teaching or suggestion that the barrier properties of a plastic ampoule having a three layered structure could be improved by using a layer of a polyolefin-polycycloolefin blend. Rather, the object of Ding is to provide a polymer suitable for fabricating rigid, semi-rigid or flexible medical devices regardless of required mechanical property. More specifically, Ding discloses that rigid

parts (such as Y-sites, filter housings in FIG. 1), semi-rigid parts (such as drip chamber 20 in FIG. 1) and flexible parts (such as medical container 12 in FIG. 1) may be fabricated from COCs as a polyolefin-polycycloolefin blend (Col. 6, lines 30-63 of Ding). These are all integral structures, not ones of multiple layers. Moreover, there is not the slightest suggestion in Ding that the blends could be used to form a layer of a multi-layered structure of any type, let alone a layer of a medical container having excellent barrier properties. Rather, the blends are intended to be used to form entire and integral structures.

Thus it is not seen how one of ordinary skill in the art looking to provide a suitable multi-layered structure for a plastic ampoule would have even considered let alone be motivated by the teachings of Ding to modify the container of Meierhoefer and Itoh as proposed. Rather, this motivation and the benefits it provides comes solely from a reading of Applicants' specification and not from anything taught by Ding. As noted in M.P.E.P. § 2142, "impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." (Emphasis added).

Accordingly, it is submitted that neither claim 1 nor claims 3, 11 and 12 dependent therefrom are obvious over this combination of references. Its withdrawal as a ground of rejection of these claims is therefore requested.

Regarding claims 13 and 15 and the rejection of the claims under § 103(a) for being obvious over Louviere in view of Itoh and Ding, Louviere is discussed in previous Replies and the comments about the reference set forth therein are incorporated herein by reference. Because the Examiner also relies on Ding in this rejection to show a

blend of a polyolefin and a polycycloolefin in an intermediate layer of a three-layer film, for the same reasons expressed above with respect to claim 1, it is submitted that it cannot be relied on to teach or suggest the intermediate layer of these two polymers as set forth in claim 13.

Accordingly, it is submitted that neither claim 13 nor claim 15 dependent therefrom are obvious over this combination of references.

It is believed claims 1, 3, 11-13 and 15 are now in condition for allowance.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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